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| 09/677,108 | 09/29/2000 | Lynn Joens | M0-4890 | 2035 |

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| EXAMINER |
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ZEMAN, ROBERT A

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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 05/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/677,108

Applicant(s)

JOENS, LYNN

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 8-21, 23-25, 27-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 8-21 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 27-29 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

BEST AVAILABLE COPY**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-17-2003 has been entered.

The amendment and response filed on 3-17-2003 are acknowledged. Claims 3-5, 27-29 and 31 have been amended. Claim 30 has been canceled. Claims 3-5, 27-29 and 31 are currently under examination.

This application contains claims 8-21 and 23-25 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the previous Office action (Paper No. 10) should have included the cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

The information disclosure statement filed on 3-17-2003 is acknowledged. An initialed copy is attached hereto.

Objections Maintained

The objection to the specification for the improper use of trademarks is maintained for reasons of record. The amendment to the specification is insufficient to overcome the objection. The specification still contains trademarks without the accompanying generic language (see page 10 for example).

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Claim Objections Maintained

The objection to claim 27 for reciting material drawn to non-elected inventions is maintained for reasons of record. As outlined previously the elected invention is drawn to **whole culture vaccines** and **inactivated tissue culture vaccines**, not inactivated *L. intracellularis* antigens. The instant claims read on a subunit vaccine that is outside the scope of the elected invention. While Applicant acknowledged said objection, he did not address it in his response.

Claim Rejections Withdrawn

The rejection of claims 27-30 under 35 U.S.C. 102(b) as being anticipated by Joens et al (U.S. Patent 5,610,059 - IDS-4) is withdrawn in light of the amendment thereto. The cited reference does not explicitly disclose compositions comprising the claimed antigen and an adjuvant.

The rejection of claims 3-4 and 27-31 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Joens et al (U.S. Patent 5,610,059 - IDS-4) is withdrawn in light of the amendment thereto. The cited reference does not explicitly disclose compositions comprising the claimed antigen and an adjuvant.

The rejection of claims 3-5 and 27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Joens et al (U.S. Patent 5,610,059 - IDS-4) is withdrawn in light of the amendment thereto.

New Grounds of Rejection***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5, 27-29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the independent claim 27 to recite, "...wherein the *L. intracellularis* has all the immunogenic characteristics of ATCC deposit No. 55370". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The specification is silent as to what other *L. intracellularis* "strains" would have an identical immunological profile as ATCC deposit No. 55370. Moreover, the specification is equally silent on which "immunological characteristics" the comparison ^{is} to be based. The specification and all working examples disclose the use of the *L. intracellularis* with the ATCC deposit number 55370 and do not even suggest the existence of other *L. intracellularis* with an identical immunological profile. Therefore this limitation is new matter.

Claims 3-5, 27-29 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising inactivated whole cell *L. intracellularis* (ATCC No. 55370) and whole cell lysates thereof, that induce the production of protective antibodies that react with *L. intracellularis* (ATCC No. 55370) antigen with a molecular weight of 21 kDa, 41 kDa, 43 kDa, 44 kDa, 60 kDa, 71 kDa or 115 kDa, does not

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reasonably provide enablement for any compositions comprising any *L. intracellularis* antigens other than inactivated *L. intracellularis* (ATCC No. 55370) and whole cell lysates thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejected claims are drawn to prophylactic compositions and their use. To be a prophylactic composition, said composition must elicit protective immunity (i.e. induce protective antibodies), demonstrable by pathogen challenge experiments, in a reasonable model system. The specification as filed, does not set forth that any antigen, other than inactivated whole cell *L. intracellularis* (ATCC No. 55370) and whole cell lysates thereof, provides any sort of protective antibody production in swine. Moreover, the specification is silent as to what other *L. intracellularis* "strains" would have an identical immunological profile as ATCC deposit No. 55370 or on which "immunological characteristics" the comparison^{is} to be based. Additionally, the specification and all working examples only disclose the use of the *L. intracellularis* with the ATCC deposit number 55370 in all their animal challenge experiments. While the skill in the art of immunology is high, to date, prediction of protective antibody production (protective immunity) for any given composition is quite unpredictable. Given the lack of success in the art, the lack of working examples and the unpredictability of the generation of protective antibodies (protective immunity), the specification, as filed, is not enabling for any composition comprising any *L. intracellularis* antigens other than inactivated *L. intracellularis* (ATCC No. 55370) and whole cell lysates thereof or their use.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5, 27-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is rendered vague and indefinite by the use of the term “protective antibodies”. It is unclear what antibodies are encompassed by said term. Are said antibodies protective against diseases where *L. intracellularis* is the etiological agent or are they protective of other maladies? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 27 is rendered vague and indefinite by the use of the phrase “*L. intracellularis* has all the **immunogenic characteristics** of ATCC deposit No. 55370”. It is unclear what “characteristics” Applicant is basing the comparison on. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 3-5, 27-29 and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Knittel et al. (WO 96/369629 – IDS-14).

Knittel et al. disclose vaccine compositions comprising inactivated whole cell *L. intracellularis* or lysates thereof and an adjuvant (see page 17-18 and Example 6) and the use of said vaccines in swine. Knittel further disclose that said bacteria can be inactivated by the addition of formalin (see page 17, lines 30-33) and that the adjuvant used could be aluminum hydroxide (see page 18, lines 1-4). It should be noted that, in the absence of evidence to the contrary, the *L. intracellularis* utilized by Knittel et al. and the instant invention are deemed to have the same immunological profile since they are the same species of bacteria. Hence, though not explicitly disclosed, the *L. intracellularis* utilized by Knittel et al. would induce the production of protective antibodies that react with a *L. intracellularis* (ATCC No. 55370) antigen with a molecular weight of 21 kDa, 41 kDa, 43 kDa, 44 kDa, 60 kDa, 71 kDa or 115 kDa. As discussed above, the immunological characteristics of a given protein are inherent features.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5 and 27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Knittel et al. (WO 96/369629 – IDS-14) in view of Joens et al (U.S. Patent 5,610,059 - IDS-4).

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The rejected claims are drawn to a an immunogenic composition comprising an **inactivated *L. intracellularis* antigen** and an **adjuvant** as well as a method of using said immunogenic composition to protect a mammal from the disease caused by *L. intracellularis*. Said antigen having all the immunological characteristics of the organism with the ATCC deposit No. 55370. Moreover, said antigen can be a protein of a given molecular weight, a whole cell, or a whole cell lysate. It should be noted that the elected invention is **limited to whole cell culture** vaccines (immunogenic compositions). The ability to induce protective antibodies is an inherent property of the microorganism (vaccine composition) since cell preparations would comprise all the antigens of the *L. intracellularis*.

Knittel et al. disclose vaccine compositions comprising inactivated whole cell *L. intracellularis* or lysates thereof and an adjuvant (see page 17-18 and Example 6) and the use of said vaccines in swine. Knittel further disclose that said bacteria can be inactivated by the addition of formalin (see page 17, lines 30-33) and that the adjuvant used could be aluminum hydroxide (see page 18, lines 1-4). Knittel et al. differ from the instant invention in that they don't explicitly disclose the use of an antigen having all the immunological characteristics of the organism with the ATCC deposit No. 55370. Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells. The isolated *L. intracellularis* is further disclosed to be inoculated into porcines in order to check its pathogenicity (see examples 1 and 2). Moreover, the isolated *L. intracellularis* disclosed by Joens et al. was deposited with ATCC with the deposit number 55370 (see column 8, lines 14-21 and claim 1) and therefore would have all the properties of the immunogen of the instant claims. Additionally, Joens et al. disclose that the *L. intracellularis* culture could be used to develop a "bacterin" using techniques known in the art such as heat treatment or chemical inactivation (see column 4, lines 6-16) said bacterin could be

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administered to porcines to "permit the pigs to mount an effective immune response against the agent (PPE)". Therefore it would have been obvious to one of skill in the art to use the antigen disclosed by Joens et al. (ATCC deposit No. 55730) in the vaccine compositions of Knittel et al. Moreover, it would have been equally obvious to use the resulting vaccine compositions to protect swine from diseases caused by *L. intracellularis* infection. The disclosure by Joens et al. that said bacterin (immunogen) could be administered to pigs to "permit the pigs to mount an effective immune response against the agent (PPE) would provide one of ^{ordinary} skill in the art not only of a reasonable expectation of success but a motivation to use the disclosed antigen (ATCC No. 55730) as a vaccine. Therefore, for the reasons set forth above, the combination of the disclosures by Knittel et al. and Joens et al. renders all the rejected claims obvious.

Conclusion

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1001

Robert A. Zeman
May 22, 2003

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